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### **SECTION II - REMARKS**

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#### Regarding the Amendments

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By the present amendment, cancellation of claims 1-19, without prejudice, and entry of new claims 20-30 are requested. New claims 20-30 are fully supported by the specification and the original claims. No new matter has been added, as defined by 35 U.S.C. § 132. Specifically, the new claims define the invention as requested by the Examiner in the Office Action mailed September 8, 2006. New claim 20 is supported on page 11, second paragraph, page 4, first full paragraph, page 15, Figure 1, page 12, second full paragraph, page 5, first full paragraph and page 7, first full paragraph of the specification. Claims 21 and 30 are supported on page 4, first full paragraph. New claims 22 and 28 correspond to original claim 2. Claims 23 and 29 correspond to original claim 3. Claims 24 and 25 correspond to original claims 5 and 6, respectively. Claim 26 corresponds to original claim 8. Claim 27 is supported on page 11, first full paragraph, in connection with page 12, second full paragraph, page 7, second and third paragraphs and Example 2.

Thus, upon entry of the amendments, claims 20-30 will be pending.

#### Objection to the Specification

The Examiner has objected to both the title of the invention and the abstract of the invention, stating that each is not sufficiently descriptive of the invention. As set forth above in Section I – Amendments, both the title and abstract of the invention have been amended. The amended title is:

"Method of Increasing the Content of Selected Transgene-Coded Proteins or Peptides in Plants"

The amended abstract is:

A method of increasing the content of one or more transgenecoded proteins or peptides in a plant is described. The increase is an effect of a decrease in the concentration of an ATP/ADP transporter in the plant. The method depends on transformation with and expression of a cDNA encoding an ATP/ADP transporter operably linked in antisense orientation to a promoter active in the plant.

As amended, both adequately and accurately describe the invention and are fully consistent with

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and supported by the original disclosure of the application. Withdrawal of the objections is respectfully requested.

### Rejection of Claims 1, 4, 9-11, 13 and 15 Under 35 U.S.C. §112

The Examiner has rejected previously pending claims 1, 4, 9-11, 13 and 15 under 35 U.S.C. §112. It is respectfully submitted that these claims have been cancelled. However, to the extent that new claims 20-30 correspond to the previously pending claims, the rejections are discussed below.

Claim 15 is rejected under 35 U.S.C. §112, second paragraph as being indefinite for lacking antecedent basis for the term "the ATP/ADP transporter." As claim 15 has been cancelled and none of the new claims corresponds to the language of former claim 15, it is respectfully submitted that the rejection is moot. Withdrawal of the rejection is therefore respectfully requested.

Additionally, clams 1, 4, 9-11, 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 1, 4, 9-11, 13 and 15 have been cancelled by the present Amendment and Response and it is therefore respectfully submitted that the rejection is moot. New claims 20-30 are not drawn to methods "comprising any change in distribution of ATP and/or ADP in any plant," as the Examiner alleged with respect to the former claims. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 1, 4, 9-11, 13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as lacking enablement. Specifically, it is stated on page 7, paragraph 6 that:

"because the specification, while being enabled for a method for increasing the concentration of a transgene-coded protein in a potato plant comprising transforming a potato plant with an antisense construct comprising a potato cDNA for an ATP/ADP transporter operably linked in antisense orientation to a promoter that functions in potato plants, does not reasonably provide enablement for any other method of increasing the content of a transgene-coded biomolecule in any other organism using any other method of changing the distribution of ATP/ADP in cells of the organism."

New claims 20-30 recite a method clearly described in the specification, i.e. antisense inhibition

of the plastidiary ATP/ADP transporter function, and do not comprise recitation of a change in distribution of ATP and/or ADP in a plant.

Furthermore, the Examiner has stated that specification does not provide any guidance for any host plant other than a potato plant, because

"of the sequence variability between the different genes in different species of plants and because of the inconsistent results taught in the prior art, there is a high degree of unpredictability in the use of antisense to inhibit the expression of different genes."

New claims 20-30 recite inhibition of a specific gene, *i.e.* the plastidiary ATP/ADP transporter gene, by an antisense construct specific thereto. Elomaa et al., cited by the Examiner, confirms that expression of two different genes, *i.e.* gchs1 and gchs2, having distinct structure and expression patterns can be blocked by antisense constructs of respective specific cDNAs. Similarly, Klee et al., cited by the Examiner, suggest application of specific antisense constructs to inhibit gene expression. Both references teach that the antisense technology is a specific method and its success is dependent on the degree of sequence homology between the target gene and the antisense gene. Thus, recitation in claims 20-30 of inhibition of a plastidiary ATP/ADP transporter gene by a specific antisense construct is consistent with the references cited by the Examiner and is fully supported by the specification, as originally filed.

A skilled person would not require undue experimentation to practice the invention, because the plastidiary ATP/ADP transporter gene is fairly conserved throughout the plants. Tjaden et al., cited by the Examiner, teach application of primers specific to sequences of a cress plastidiary ATP/ADP transporter (AATP1 of *Arabidopsis thaliana*) for screening a potato cDNA library to detect a potato plastidiary ATP/ADP transporter (see page 538, 3<sup>rd</sup> paragraph). Similarly, Häusler et al., also cited by the Examiner, teach screening of a cDNA library of tobacco with the TPT gene of potato (see page 367, 1<sup>st</sup> paragraph of Materials and Methods). Therefore, the DNA sequence for a specific target ATP/ADP transporter gene in a given plant species can be easily retrieved from databanks or cDNA libraries. Hence, no undue experimentation is required to make an appropriate specific antisense cDNA construct for the plastidiary ATP/ADP transporter gene.

Accordingly, withdrawal of the rejection is respectfully requested.

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## Rejection of Claims 1, 4, 9-11, 13 and 15 Under 35 U.S.C. §102

The Examiner has rejected previously pending claims 1, 4, 9-11, 13 and 15 under 35 U.S.C. §102(b) as anticipated by Häusler et al. taken with evidence of Bevan M and as anticipated by Tjaden et al., taken with the evidence of Bevan M. It is respectfully submitted that these claims have been cancelled. However, to the extent that new claims 20-30 correspond to the previously pending claims, the rejections are discussed below.

Anticipation of a claim requires the disclosure in a single prior art reference of each element of the claim under consideration. (In re Spada, 15 USPQ2d 1655 (Fed. Cir., 1990), In re Bond, 15 USPQ2d 1566 (Fed. Cir., 1990). As neither Häusler et al. nor Tjaden et al. teach all of the elements of the claimed invention, neither anticipates new claims 20-30.

Specifically, the claims have been rejected as anticipated by Häusler et al. or Tjaden et al., as it is alleged that each teaches a method of making transgenic plants comprising an antisense construct that suppresses the expression of the endogeneous ATP/ADP transporter by using a vector which expresses NPTII as a transgene-coded protein. Therefore, the accumulation of NPTII is inherently raised in both references.

NPTII is used as a marker for the selection of transformed plant cells (page 12, 2nd full paragraph; also Bevan, cited by the Examiner). It is obvious from the full content of the present specification that the purpose of the invention is to accumulate proteins other than marker enzymes such as NPTII (see e.g. paragraph overlapping pages 6 and 7 of the specification in connection with page 5, 1st full paragraph).

Additionally, independent claims 20 and 27 as set forth above recite expression of the antisense ATP/ADP, a marker and "one or more <u>further</u> desired transgenes." (Emphasis added.) Therefore, the new claims are distinguished from the methods disclosed by Häusler et al. and Tjaden et al. in that the claimed method includes further transformation with one or more desired transgenes besides a cDNA of the plastidiary ATP/ADP transporter in antisense orientation and a selectable marker gene (e.g. NPTII).

As neither Häusler et al. taken with evidence of Bevan M nor Tjaden et al. taken with the evidence of Bevan M describes a method of increasing the content of one or more desired transgenic proteins or peptides as set forth in new claims 20-30, neither Häusler et al. nor Tjaden et al. anticipate the claimed invention. Accordingly, withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

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# **CONCLUSION**

Based on the foregoing, all of Applicants' pending claims 20-30 are patentably distinguished over the art, and are in form and condition for allowance. The Examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

No fees are believed to be due for the filing of this paper. However, should any fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Date: 1/8/07

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Respectfully submitted,

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